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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/606,222	THOMAS ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 0312*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-24,32 and 43-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-24, 32, 43-630* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendment and Response, filed 2/9/06, has been entered. Claims 20, 43, 49 are amended; claims 58-63 are newly added; claims 20-24, 32, 43-63 are pending and under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-24, 32, 43-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection, necessitated by Applicants' amendment to the claims. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Applicants' have now amended the claims to recite that the DNA molecule for removing a nucleic acid sequence comprising, "flanked by recombinase sites in a single nucleotide chain, ..." See claim 20 (emphasis added). This limitation is not supported by the instantly-filed disclosure, and is considered new matter. Applicants point to support for this amendment in Example 1, which explains construction of "the" cassette, and to Figure 2A and the text relating to the figure (p. 3, lines 7-25), and Example 2, to show a single nucleotide chain, with two recombinase sites. Applicants argue that support for matter need not be verbatim, and that by disclosing an invention has a particular function/property, the

application necessarily discloses that function or property. Therefore, Applicants argue that the application can be amended to recite this property without introducing new matter (MPEP §2163.07(a)). Applicants argue that these amendments do not introduce new matter and do not alter the scope of the claims, and that the amendment clarifies that the recited elements are one DNA molecule, and not two or more molecules which contain the recited elements. See page 13 of Applicants' Response.

This is not persuasive. The phrase "in a single nucleotide chain" fails to find support in the specification. A "single nucleotide chain" can encompass, for example, single stranded nucleotide chains (including RNA or DNA chains). Furthermore, as amended, it appears that the recombinase sites are in a single nucleotide chain, which is not contemplated by the instant specification (see also, further discussion, under 112, 2nd paragraph rejection, below). Although the specification does contemplate the variously recited elements to be present in a particular vector (such as Figure 2A), it does not contemplate the breadth of the claims, as instantly amended, wherein the DNA molecule comprises, flanked by recombinase sites in a single nucleotide chain, a spatially or temporally restricted promoter operably linked to a recombinase gene and a nucleic acid sequence to be removed. MPEP §2163.02 states that although the subject matter need not be described literally in order for the disclosure to satisfy the description requirement, it states that, "If a claim is amended to include subject matter, limitations, or termination not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application, as filed, the examiner should conclude that the claimed subject matter is not described in that application." In the instant case, the phrase "in a single nucleotide chain" fails to find support in the as-filed application and thus, constitutes new matter.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 20-24, 32, 43-63 are also rejected under 35 U.S.C.

112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the

subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-24, 32, 43-45, 49-56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dymecki [**U.S. Pat. No.** 6,774,279 B2, published August 10, 2004, filed May 30, 1997] when taken with Von Melchner *et al.* [WO 97/07223, Published 27 February 1997] in further view of Abuin *et al.* [**Mol. And Cell. Bio.**, 16(4):1851-1856 (April 1996)].

The claims, as amended, are now directed to a DNA molecule for removing a nucleic acid sequence that has been inserted into a host cell, the DNA molecule comprising, glanced by recombinase sites in a single chain, (a) a spatially or temporally restricted promoter operably linked to a b) recombinase gene, c) said nucleic acid sequence to be removed. In further embodiments, the claims are directed to methods for deleting a nucleic acid sequence from a mouse cell genome in a regulatable manner using said nucleic acid sequence, and a transgenic mouse comprising said DNA sequence. In specific embodiments, the recombinase site can be loxP or FRT and the recombinase gene can be Cre or FLP; the nucleic acid sequence is a wild-type allele or fragment thereof of a gene.

Applicants' Arguments. Applicants' argue that the combination of Dymecki and Von Melchner *et al.* do not teach the claimed invention. Applicants argue that Von Melchner teaches using retroviral vectors in order to transduce foreign genes in to mammalian cells, and that Figure 9-A, which is relied upon in the prior Office action and the combination of art, including Dymecki, Von Melchner and Abuin fail to arrive at the claimed invention. Applicants argue that 1) Dymecki does not teach

a single transgene, but used to teach use of site-specific recombinases to alter genomic DNA, that 2) Von Melchner teach the claimed DNA molecules, methods which use the molecule, and a transgenic mouse containing it. Applicants submit that the office's interpretation of the teachings of Von Melchner *et al.* is not accurate, because they do not teach or suggest a DNA molecule, wherein a promoter is operably linked to a recombinase gene, and the nucleic acid to be removed. Applicants argue that Von Melchner do not teach or suggest that the target sequence is present in a single vector, with two flanking sequences in a single nucleotide chain. See pages 8-9 of the Response. Applicants argue that because Von Melchner teach a "system" where a target sequence-flanked DNA is excised, and that this system involves the insertion of two separate vectors into the cell, each of which contains one recombinase site, wherein the vectors subsequently recombine in vivo to duplicate the recombinase site, thereby generating a self-excision construct that contains two flanking recombinase target sites. Applicants argue that the retroviruses of the invention duplicate the target sequences, which enables the recombinase to delete the desired sequence, and thus, the flanking target sequences are only created *in vivo*, and thus, do not exist in the vectors used by Von Melchner. Applicants argue that the claimed DNA molecule is a single piece of DNA that contains the claimed components, and that Von Melchner do not teach the claimed invention. Applicants argue that Figure 9A, which is cited in the prior Office action is the predicted structure of the provisuses *in vivo*, and then the recombined product, thus, Applicants argue that Von Melchner never had possession of the DNA which is instantly-claimed. See pages 9-10 of the Response.

Response to Arguments. These arguments are considered, but not found to be persuasive. The combination of the cited art arrives at the claimed invention, because 1) Dymecki teach site-specific recombination of DNA using Cre recombinase and 2) Von Melchner teach methods to produce a self-deleting vector that contains flanking targeting sequences, as required by the claims. It is not relevant whether

the vector is made *in vitro* or *in vivo*, Von Melchner provide teachings to produce the single transgene, as required by the claims. Furthermore, under §103, the only conditions that are required to be met are that 1) the claimed invention must be considered as a whole, b) the references must teach or suggest the desirability and thus, the obviousness of making the combination, c) that the references must be viewed without the benefit of impermissible hindsight and d) that there is a reasonable expectation of success. The Examiner is unaware of any passage of the MPEP that requires the prior art to be in possession of the claimed invention. Because the combination of art teaches the specific components of the instantly-claimed DNA molecule, because it provides the requisite motivation to arrive at the claimed invention, with a reasonable expectation of success, it is maintained that the combination of the art is proper.

Applicants' Arguments. Applicants argue that the cited references do not provide any motivation to modify their teachings with regard to a two component vector system to achieve what is instantly-claimed, because there is no indication that the same results would occur if the vector were produced to comprise a DNA molecule that contains all of the components of the excision system that are recited in claim 1. Applicants argue that although Von Melchner sometimes refer to "at least one" target sequence in their vector system or in cells, the sequence to be deleted and the recombinase are not flanked by two recombinase sites in a single DNA vector, because if this were done using the methods of Von Melchner, the nucleic acid between the sites would be excised during vector production, removing the recombinase, whereas the goal in Von Melchner was to insert the material into the mammalian genome and then excise the desired nucleic acid. Applicants argue that because Von Melchner use a two vector reagent in order to propagate DNA in bacteria without premature excision of the cassette, they do not provide teachings or suggestion of using a single DNA with two recombinase sites, as instantly claimed. Applicants argue that Dymecki and Abuin *et al.* only disclose the function

of site-specific recombinases and their potential uses in technologies, such as gene therapy. There is nothing to motivate the skilled artisan to modify Von Melchner to create a single DNA method, and no reasonable expectation that this approach would be successful. See pages 10-11 of the Response.

Response to Arguments. Applicants' arguments are not persuasive. The arguments of counsel cannot take the place of evidence in the record. See *In re* Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) and MPEP §716.01. Applicants have not provided an appropriate affidavit or declaration supporting that the methods as taught by Von Melchner *et al.* when combined with Dymecki's teaching would not result in the components as required by the claims. They teach the predicted structure of the proviruses before and after site-specific recombination, and provide teachings with regard to the structural limitations of the claims. Furthermore, Von Melchner teach that that the site-specific recombinases can be on one vector (as shown in Figure 9A). Accordingly, it is maintained that one of skill in the art, given the combined teachings, could arrive at the claimed invention with a reasonable expectation of success, and with the requisite motivation.

Dymecki teach methods of site-specific recombination of DNA into the genome of a mammal. See Abstract. Particularly, they teach methods utilizing either Flp or Cre recombinases to introduce specific deletions into the mouse genome. They teach that a two recombinase system would allow for efficient use of the first recombinase to generate a mutation, and the second recombinase to remove selectable markers, which can confound interpretation of study. See col. 2, lines 1-15. They teach methods of *in vivo* genetic engineering utilizing Flp (or Cre) recombinase activity to catalyze site-specific recombination in cells, which can include germ line cells or somatic cells. See col. 2, lines 53-65. Further, that this system can be used in various methods, such as in activation of ectopic expression of a gene during development, inactivation of a gene at a specific time, or in a specific

tissue, or identifying a cell lineage by activation or inactivation of a gene. The gene that is studied using this method can be varied, for example, a developmental gene, an essential gene, or a selectable marker. See col. 4, lines 1-10. They teach that the non-human mammal can have this genetic material stably or excisably integrated into its genome, and that it can be transmitted through the germ line to succeeding generations. They teach that the mammal can include mice, and that the introduction of the transgene can be made by various methods known in the art. See col. 4, lines 23-57. They teach that a controlled recombinase target site can be used to engineer tissue-specific mutations, or to assess the effect of ectopic expression in a subset of cells, within an otherwise normal organism, and that this method is particularly useful in cases of studying the effect of lethal or otherwise deleterious mutations, or where the null mutations of a gene do not result in an observable phenotype. See col. 6-7, bridging ¶. They teach that the particular transgene can have the recombinase operably linked to a regulatory region, wherein this regulatory region can be a promoter, enhancer, etc. These regulatory regions can be regulated by, for example, developmental stage, or particular factors. See col. 8, lines 29-67. Dymecki teach that Cre/*loxP* can be used to control a series of recombination events by expression the Flp and Cre recombinases independently of each other; particularly, wherein the second transgene encodes a marker, for example, to trace cell lineages. See col. 10-11, bridging paragraph.

Dymecki do not teach that the transgene is a single transgene wherein the transgene is flanked by recombinase sites. However, prior to the time of the claimed invention, Von Melchner *et al.* teach self-deleting vectors for gene therapy. In particular, they teach utilizing retroviruses to introduce genes into mammalian genomes. See p. 2, 2nd full paragraph. In particular, they teach that retroviral vectors are the most efficient means to transduce foreign genes into mammalian cells (page 3, 1st full ¶) and that such a vector would contain site-specific recombinases, such as Cre and loxP, or Flp and frt. Particularly, they teach that

that the site-specific recombinase can be within one vector (or encoded in a separate vector). See p. 4. They teach that these vectors can then be deleted after introduction into the mammalian cell genome, for example, to remove proviral genome sequences (see p. 5, 3rd paragraph). In particular, they teach a vector that is flanked by recombinase sites (loxP), has a promoter operably linked to a recombinase gene, and a nucleic acid of interest to be deleted. See Figure 9-A.

Accordingly, in view of Dymecki and Von Melchner *et al.*, it would have been obvious for one of skill in the art to modify the techniques to produce transgenic non-human mammals, as taught by Dymecki, using a vector as taught by Von Melchner *et al.*, in order to excise a gene of interest (such as a marker gene), with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to make such a modification, as Dymecki contemplate removal of selectable markers, because they may interfere with the study of the resultant animal, and Von Melchner teach that their vectors can be used to introduce site-specific mutations into the mammalian genome. Abuin *et al.* provide further motivation, as they teach that it is an art-recognized goal to excise selection markers when producing transgenic mice. For example, they state that one would want to remove selectable markers in order to increase the manipulations that can be done, or for analysis. See Abstract. Furthermore, they teach that, "[T]he exogenous promoter and enhancer elements required for the expression of these selectable markers have the potential to interfere with endogenous regulatory elements present in the vicinity of the targeted mutation. Therefore, it may be sometimes advantageous to remove selectable markers after gene targeting." See p. 1851, 2nd column, 1st paragraph. Abuin *et al.* further contemplate utilizing the Cre/*loxP* system in order to excise these exogenous markers (see p. 1851, 2nd paragraph). They teach that the excision of markers provide several advantages in the production of transgenic animals by allowing for additional targeting events at different loci and allows for the use of selection-based assays to study the cellular

roles and functional interactions between genes, it would alleviate any interference of expression, and to allow for an unlimited number of targeting events in mammalian cell lines which can be used in subsequent genetic analysis. Furthermore, by excision of a selectable marker, could provide for a system to assay genes whose functions are assayed at the cellular level. See p. 1855, 2nd column, last paragraph.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 46-48 and 57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dymecki [**U.S. Pat. No.** 6,774,279 B2, published August 10, 2004, filed May 30, 1997] when taken with Von Melchner *et al.* [WO 97/07223, Published 27 February 1997] in further view of Abuin *et al.* [**Mol. And Cell. Bio.**, 16(4):1851-1856 (April 1996)], as applied to claims 20-24, 32, 43-45, 49-56 above, and further in view of Vidal *et al.* [**Mol. Reprod. And Dev.**, 51:274-280 (1998)].

Applicants argue as above, that the combined art fails to teach or suggest the claimed invention. These arguments have been addressed in the rejection above. With regard to Applicants' arguments that the inventive method, which employs an intron in the recombinase sequence to overcome premature excision of the gene (see page 12 of the Response), Applicants are arguing limitations that are not in the claims.

Dymecki, Von Melchner and Abuin are described above. Although Dymecki contemplate utilizing promoters which can be used in order to express a transgene during a specific developmental stage or tissue, they do not specifically teach utilizing a male or female gamete-specific promoter. However, prior to the time of the claimed invention, Vidal teach the generation of transgenic mice using a testicular Cre recombinase driven by promoter sequences derived from synaptonemal complex protein 1 (*Sycp1*), which is expressed in an early stage of

male meiosis. They teach utilizing two transgenes, one with the *Sycp1-Cre* transgene, and one wherein the *LoxP* sites flank the βgeo coding region, the *Pgk1* promoter, or the *tk-neo* cassette inserted into the Rxrα locus. See Abstract, and Methods & Materials. In particular, Vidal teach that using Cre/*LoxP*, one can introduce predetermined mutations into the mouse genome, however, many of these mutations can result in early lethal phenotypes. Thus, by the use of temporal and spatial control of recombinase (utilizing tissue-specific or induce promoters), one could overcome these limitations. Vidal specifically teach that Cre expression can be used to target testicular germ cells to generate mutations at predetermined loci during meiosis, to define the role, in spermatogenesis, of any gene of interest. See p. 274, col. 1-2, bridging paragraph.

Accordingly, in view of the combined teachings, it would have been obvious for one of ordinary skill in the art to modify the vector, as taught by Dymecki, Von Melchner and Abuin, to utilize a gamete-specific promoter, such as *Sycp1*, as taught by Vidal *et al.*, with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to make such a modification, as Dymecki clearly teach using tissue or developmentally-specific promoters, and Vidal *et al.* teach that utilizing a gamete-specific promoter, such as *Sycp1*, would be useful in studying gene function during spermatogenesis.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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